DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

June 5, 2002

VIA FEDERAL EXPRESS – NEXT DAY

Mr. Tommy D. Carroll
410 Clear Creek Road
Chuckey, TN 37641

Warning Letter No. 02-NSV-28

Dear Mr. Carroll:

An inspection of your operation located in Chuckey, Tennessee, by our investigator on April 24, 2002 confirmed a cow purchased and sold by you on or about August 22, 2001 for slaughter for human food at [redacted], through [redacted], and [redacted], was in violation of 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

USDA/FSIS analysis of tissue collected from this animal disclosed the presence of 3.8 parts per million (ppm) gentamicin in the kidney tissue. There is no established tolerance for gentamicin in cattle (Title 21, Code of Federal Regulations (21 CFR), 556.300). The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

You should take prompt action to correct the above violation and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce the adulterated animal. As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act. To avoid future illegal residue violations, you should take precautions such as:

1. implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;
2. implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and
3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should be aware that it is not necessary for you to have personally shipped an animal in interstate commerce to be responsible for a violation of the Act. The fact that you purchased an adulterated animal which was subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

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Enclosure:
21 CFR 556.300